US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD HONEY BEE - ACUTE ORAL LC₅₀TEST Non-guideline

1. **CHEMICAL**: Mesosulfuron-methyl

PC Code No.: 122009

2. TEST MATERIAL: Hoe 130060 00 ZC96 0002

Purity: 96.0%

3. <u>CITATION</u>:

Author: Waltersdorfer, A.

Title: Code: Hoe 130060 00 ZC96 0002 Oral toxicity (LD50) to

honey bees (Apis mellifera L.)

Study Completion Date: November 20, 1996

Laboratory: Hoechst Schering AgrEvo GmbH

Umweltforschung, Oekobiologie D-65926 Frankfort am Main Federal Reublic of Germany

Sponsor: Hoechst Schering AgrEvo GmbH, Umweltforschung

D-65926 Frankfort am Main, Federal Reublic of Germany

Laboratory Report ID: CW 96/032

DP Barcode: D284719

MRID No.: 45386318

4. REVIEWED BY: Rebecca Bryan, Staff Scientist, Dynamac Corporation

Signature: Reticio Bigan

Date: 8/22/03

APPROVED BY: Teri S. Myers, Ph.D., Staff Scientist, Dynamac Corporation

Date: 8/22/03

Signature: Olushyn 5. APPROVED BY: Tim Bargar Leo La Sota

Signature: La La

Date: 0//01/04

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6. STUDY PARAMETERS:

Scientific Name of Test Organism: Apis mellifera L.

Age or Size of Test Organism at Test Initiation: Not reported

Type of Concentrations: Nominal

Definitive Study Duration: 72 hours

7. CONCLUSIONS:

The honey bee, Apis mellifera L., was exposed to Mesosulfuron-methyl as Hoe 130060 00 ZC 96 0002 for 72 hours, at ingested concentrations of 0.02, 0.20, 1.5, 15.8, 184.8 µg a.i./bee. By 72 hours, 17, 22, 23, 30, and 33% mortality was observed in the 0.02, 0.20, 1.5, 15.8, 184.8 µg a.i./bee treatment groups, respectively, compared to 4% mortality in the control group. The study author reported a LD₅₀ value of 5.6 µg a.i./bee. As a result, mesosulfuron-methyl is categorized as moderately pentoxic to honeybees on an acute oral basis.

but this one was conducted for a different lingth of time.

This acute contact study is classified as Supplemental. This acute oral study is scientifically sound, but it is a non-guideline study and does not fulfill an OPP guideline requirement.

Reported Statistical Results:

LD₅₀: 5.6 μg a.i./bee 95% C.I.: Not reported

NOEC: Not reported Probit Slope: N/A

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8. ADEQUACY OF THE STUDY:

A. Classification: The acute oral study is scientifically sound and is classified as Supplemental.

B. Rationale: This acute oral study is scientifically sound and is classified as Supplemental because the study is a non-guideline study and does not fulfill an OPP guideline requirement.

C. Repairability: N/A

9. **GUIDELINE DEVIATIONS**:

N/A

10. <u>SUBMISSION PURPOSE</u>: This non-guideline study was submitted to provide data on the acute oral toxicity of mesosulfuron-methyl to honeybees for the purpose of chemical registration.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information		
Species:	Apis mellifera		
Age at beginning of test:	Not reported		
Supplier:	Laboratory colonies.		
All bees from the same source?	Yes, from healthy hives.		

B. Test System

Guideline Criteria	Reported Information		
Cage size adequate?	The cages were made of wire mesh. Cage was 12-13 cm high with a 5 cm diameter.		
Lighting:	16 hours light/8 hours dark photoperiod		
Temperature:	26.5-28°C		
Relative humidity:	70-76%		

C. Test Design

Guideline Criteria	Reported Information		
Range finding test?	No range finding study was conducted.		
Reference toxicant test?	The reference toxicant Triazophos was used. The test concentrations were 0.00012, 0.00024, 0.00048, 0.000096, and 0.00192% a.i. in diet (Actual ingested doses were 0.0219, 0.0265, 0.0738, 0.1223, and 0.2331 µg a.i./bee). The test substance was mixed with bee food (mixture of powdered sugar, honey, and water).		
Method of administration:			
Nominal doses:	0.0001, 0.001, 0.01, 0.1, and 1.0% a.i. in diet (Actual ingested doses were 0.0204, 0.2038, 1.4994, 15.8080, and 184.8100 μg a.i./bee).		
Controls:	negative control		
Number of colonies per group:	5 replicates; 10 bees/replicate		
olvent:	N/A		

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Guideline Criteria	Reported Information		
Feeding:	The bees were fed the bee diet mix with test substance for 5 hours. Then, the bees were supplied with untreated 50% sucrose solution, ad libitum.		
Observation period:	Dead and damaged bees were recorded 24, 48, and 72 hours after application.		

12. <u>REPORTED RESULTS</u>:

Guideline Criteria	Reported Information		
Quality assurance and GLP compliance statements were included in the report?	Yes		
Control performance:	4% mortality by 72 hours.		
Raw data included:	Percent mortality for each treatment group w provided; replicate data were not.		
Signs of toxicity (if any) were described?	None reported.		

Mortality

Dosage % a.i./bee		Percent Mortality (%)		
(actual intake: μg		Hour of Study		
a.i./bee)	No. of bees	24	48	72
Test Substance (Hoe 1 Control Group	30060 00 ZC 96 00 50	02)		
0.0001 (0.02)	50	0	6	17
0.001	50	0	13	22

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Dosage % a.i./bee			Percent Mortality (%)	
% a.i./bee (actual intake: μg		Hour of Study		
a.i./bee)	No. of bees	24	48 .	72
0.01 (1.5)	50	11	17	23
0.1 (15.8)	50	3	14	30
1.0 (184.8)	50	0	16	33
Toxic Standard (Triazo	phos):			
Control	50	0	3	4
0.00012 (0.02)	50	36	36	38
0.00024 0.03)	50	31	32	32
0.00048 0.07)	50	48	48	48
.00096	50	46	46	46
00192	50	50	50	50

Observations: By 72 hours, 17, 22, 23, 30, and 33% mortality was observed in the 0.02, 0.2, 1.5, 15.8, 184.8 μ g a.i./bee treatment groups, respectively, compared to 4% mortality in the control group.

Statistical method: The LD_{50} values were calculated using SAS probit analysis.

Reported Statistical Results:

LD₅₀: 5.6 μg a.i./bee

95% C.I.: Not reported

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NOEL: Not reported

Probit Slope: N/A

13. <u>VERIFICATION OF STATISTICAL RESULTS</u>:

Statistical method: The 72-hour LD_{50} value was visually determined because mortality did not exceed 50% in this study. The NOEC could not be statistically determined because replicate data were not provided.

Results:

 LC_{50} : >184.8 μg a.i./bee

95% C.I.: N/A

NOEC: Not determined

Probit Slope: N/A

14. REVIEWER'S COMMENTS:

The reviewer's conclusions did not agree with the study author's. Mortality did not exceed 50% in this study, so the reviewer determined that the LD $_{50}$ exceeded the highest dose, 184.8 μ g a.i./bee. The study author determined the LD $_{50}$ to be 5.6 μ g a.i./bee. Because the study author's value is more conservative, it is reported in the Conclusions section.

The 48-hour LD $_{50}$ of the toxic standard, Triazophos, was 0.013 μg a.i./bee. This value was determined by the SAS probit analysis.

15. REFERENCES:

Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. EPPO Bulletin 22, 203-215 (1992) No. 170.-600/4-85/013.

The SAS System for Windows, Release 6.10 TS Level 0019, 1991.

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